



981000041  
pharmacists planning service, inc.

101 Lucas Valley Road, Suite 210 • San Rafael, California 94903  
Tel: (415) 479-8628 • Fax: (415) 479-8608 • e-mail: ppsi@aol.com

3939 '99 JUN 17 P3:28

May 25, 1999

Janet Woodcock, M.D.  
Director, Center for Drug Evaluation  
and Research  
Department of Health & Human Services  
FDA Administration  
Washington, D.C. 20857

RE: Docket No. 98P -0169/CP1

Dear Dr. Woodcock:

This is a follow-up to your September 18, 1998 letter regarding PPSI's Citizen Petition requesting the FDA instituting standards for the labeling of botanicals, homeopathics, nutritionals, and natural products which would be similar to the labeling requirements for over-the-counter (OTC) drugs.

Enclosed for your review and comments and to be made part of Docket No. 98P -0169/CP1 are the following:

1. Information on Saw Palmetto (five papers)
  - a. Jama, November 11, 1998, "Saw Palmetto Extracts  
for Treatment of Benign Prostatic Hyperplasia - A Systematic Review"
  - b. "Efficacy of a Combined Sabal-Urtica Preparation in the Treatment of Benign Prostatic Hyperplasia (BPH)" by Metzker, Kieser & Holscher
  - c. Extracacta "Sabal Extract WS 1473 in Benign Prostatic Hyperplasia" by Redecker & Bahnhofstrasse
  - d. Urologe "A Combination of Sabal and Urtica Extracts vs. Finasteride in BPH (Stage I to II acc. to Alken: A Comparison of Therapeutic Efficacy in a One Year Double Blind Study"
  - e. Uro "Efficacy of Saw Palmetto Fruit Special Extract WS 1473 in Patients with Alken Stage I-II Benign Prostatic Hyperplasia - Open Multicentre Study" by Ziegler & Holscher

98P-0169

C3

Janet Woodcock, M.D.  
May 25, 1999  
Page Two

2. Information on Ginkgo Biloba (four papers)

- a. JAMA, October 22/29, 1997 "A Placebo Controlled, Double-blind, Randomized Trial on an Extract of Ginkgo Biloba for Dementia"
- b. "Proof of Efficacy of the Ginkgo Biloba Special Extract EGb 761 in Outpatients Suffering From Mild to Moderate Primary Degenerative Dementia of the Alzheimer Type or Multi-Infarct Dementia"
- c. Human Psychopharmacology "A Double Blind Placebo-controlled Trial of Tanakan in the Treatment of Idiopathic Cognitive Impairment in the Elderly"
- d. American Journal of Therapeutics "Central Nervous System Effects of Ginkgo Biloba, A Plant Extract"

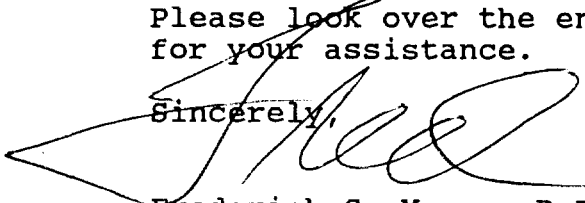
Again, what we are asking for is OTC labeling for those drugs which cause ADRs. I am enclosing a copy of the American Pharmaceutical Association's (APhA) Herbal Chart for Health Care Professionals by June H. McDermott, M.S. Pharm. MBA and Peter Curtis, M.D. from the School of Pharmacy and Family Medicine, University of North Carolina at Chapel Hill with the ADRs on these two specific products. Please note that four major drugs being highly used inhibit platelet aggregation and increased fibrinolytic activity or decrease platelet adhesiveness. Also, please note the number of drugs which should not be taken while pregnant because of the variable effects on INR. These charts were put in the APhA monthly newsletter a year ago.

Perhaps we can prevail on Edward J. Tapper, M.D., V.P., Medical and Clinical R & D, Warner-Lambert Company or Art Ullene, M.D., who make an entire line of nutritional supplements, to put at least the pregnancy warnings on some of their products.

We welcome any suggestions you have as head of FDA's Center for Drug Evaluation and Research. Have you done a recent education and awareness campaign to consumers? If not, is this doable or possible so at least consumers can be made aware of the possible problems.

Please look over the enclosed and get back to me. Thank you for your assistance.

Sincerely,



Frederick S. Mayer, R.Ph., M.P.H., President

Enclosures

Warner-Lambert Company  
4914 Lambert Place  
Dublin, VA 24084

**WARNER  
LAMBERT**

Dear Healthcare Professional:

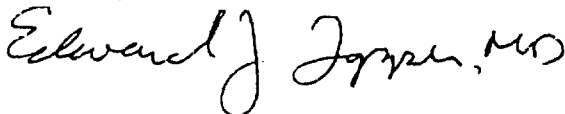
Thank you for responding to our recent introduction of standardized herbal extracts from Warner-Lambert.

As you requested, we have enclosed reprints of key clinical studies on Ginkgo biloba extract EGb 761\* and a liposterolic Saw Palmetto extract. You will also receive a separate mailing with information pamphlets to help introduce these extracts to your patients.

Healthcare professionals are being asked more and more frequently by their patients about herbal supplements, so we very much understand and appreciate your desire to learn more about these products. We trust that you will find these enclosed studies to be informative. We also hope that they will help you make informed decisions about integrating these herbal supplements into your practice.

If you have questions or comments, please call Warner-Lambert toll free at 1-800-524-2854.

Sincerely,



Edward J. Tapper, M.D.  
V.P., Medical and Clinical R&D  
Warner-Lambert Company

encs.



# pharmacists planning service, inc.

101 Lucas Valley Road, Suite 210 • San Rafael, California 94903  
Tel: (415) 479-8628 • Fax: (415) 479-8608 • e-mail: ppsi@aol.com

May 25, 1999

Edward J. Tapper, M.D.  
Vice President, Medical & Clinical R & D  
Warner-Lambert Company  
4914 Lambert Place  
Dublin, VA 24084

Dear Dr. Tapper:

Many, many thanks for sending along the four research papers on Ginkgo Biloba and the five papers on Saw Palmetto which we have sent on to Janet Woodcock, M.D., FDA. Please send me another set of the above for our records.

PPSI, a 501 C (3) non-profit public health, consumer interest organization would like to see how we can partner with Warner-Lambert on educating health care professionals regarding some of the adverse drug reactions (ADRs) and drug interactions which are associated with some of these nutritional products. We realize that under FDAMA that no labeling is required for these products, but I think it would be prudent for Warner-Lambert, one of the major pharmaceutical companies in the United States, to help educate professionals and consumers on some of these ADRs.

We would welcome any suggestions or thoughts you have on how consumers, patients and health care professionals can be educated and what Warner-Lambert is doing in this field.

I am especially cognizant of the paper entitled "Central Nervous System Effects of Ginkgo Biloba, a Plant Extract" in which in the summary the researchers state "it was established that the electro-physiological effects of EGb in CNS are similar to those of well known cognitive activators such as 'nootropics' as well as tacrine, the only marketed 'antidementia' drug currently available in the United States". If it has the same biological activity as the prescription drug, Tacrine, shouldn't FDA consider this as a drug and not a nutritional supplement? Shouldn't we be getting this type of information out to consumers, patients and health care professionals?

Again, thank you for going the first step in educating health care professionals who request information with some quality studies which we have not previously received from other companies or drug manufacturers of alternative medicines. We look forward to hearing from you and working together on this important issue.

Sincerely,

Frederick S. Mayer, R.Ph., M.P.H., President



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

SEP 18 1998

Frederick S. Mayer  
President  
Pharmacists Planning Service, Inc.  
101 Lucas Valley Road  
Suite 210  
San Rafael, California 94903

Re: Docket No. 98P-0169/CP1

Dear Mr. Mayer:

I am writing to inform you that the Food and Drug Administration has not yet resolved the issues raised in your citizen petition submitted on March 16, 1998. Your petition requests that the Agency institute standards for the labeling of botanicals, homeopathics, nutritionals, and natural products that would be similar to the labeling requirements for over-the-counter drugs.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

A handwritten signature in black ink, which appears to read "Janet Woodcock", is written over a horizontal line.

Janet Woodcock, M.D.  
Director  
Center for Drug Evaluation and Research



# pharmacists planning service, inc.

101 Lucas Valley Road, Suite 210 • San Rafael, California 94903  
Tel: (415) 479-8628 • Fax: (415) 479-8608 • e-mail: ppsi@aol.com

May 25, 1999

Janet B. McDonald, Ph.D., RD  
US Public Health Service  
1431 Harbor Bay Parkway  
Alameda, CA 94502 -7070

Dear Janet:

Many, many thanks for the phone call. Yes, I plan to attend the FDA hearing scheduled for July 20th, 1999 from 9:00 a.m. - 5:00 p.m. in Oakland. Please send me registration information. I would like to testify at this hearing on drug interactions and adverse drug effects (ADEs) on nutritionals, alternative medicine and herbs.

Will there be room for the Gray Panthers or other folks who wish to testify?

I have written the enclosed letter to Janet Woodcock, M.D., Director, Center for Evaluation and Research, FDA, regarding our March 16, 1998 Citizen's Petition filed with the FDA for the labeling of botanicals, homeopathics, nutritionals and natural products which would be similar to the labeling requirement for over-the-counter (OTC) drugs.

Please send me the particulars of the upcoming hearing. Many, many thanks for your assistance in putting together the FDA Town Hall Meeting in Oakland on May 12, 1999. We have arranged for some of our concerns and a group meeting with Richard Baldwin on Monday, August 9, 1999. We will discuss some of our prescription drug concerns including the alternative drug labeling issues.

Sincerely,

Frederick S. Mayer, R.Ph., M.P.H.  
President

Enclosure

cc: Larry Sasich, Public Citizen	202 588-7796
Richard Baldwin, FDA	510 637-3976
Janet Woodcock, M.D.	
Joanne Ikeda, UC Berkeley	510 642-0535
Joe Cranston, R.Ph., Ph.D., AMA	312 464-4184
Lucinda Maine, R.Ph., Ph.D., APhA	202 783-2351



pharmacists planning service, inc.

Frederick S. Mayer

Pharm B., M.P.H.  
President

101 Lucas Valley Road, Suite 210  
San Rafael, California 94903

Tel: (415) 479-8628  
Fax: (415) 479-8608

E-Mail: [ppsi@aol.com](mailto:ppsi@aol.com)



# pharmacists planning service, inc.

101 Lucas Valley Road, Suite 210 • San Rafael, California 94903  
Tel: (415) 479-8628 • Fax: (415) 479-8608 • e-mail: ppsi@aol.com

*Dr. Woodcock  
Some of our programs  
Post  
[Signature]*

Dear Colleague:

Many, many thanks for your recent request for information on PPSI's public health programs.

PPSI is a non-profit organization and the originator of over thirty-five national programs. Due to limited funds we are requesting a \$15.00 charge for each kit ordered.

Please check off appropriate boxes or requests and return with your remittance of \$15.00 for each kit.

Many, many thanks for your interest and request.

Sincerely,

Joseph I. Rotenberg, R.Ph.  
Vice President, Professional Affairs

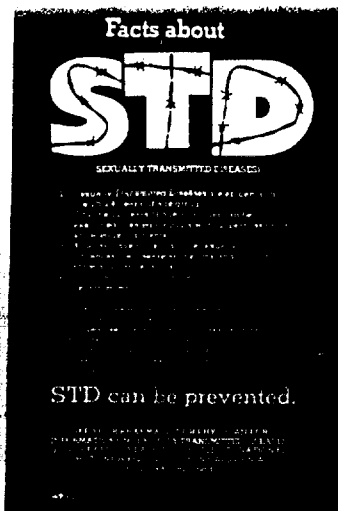
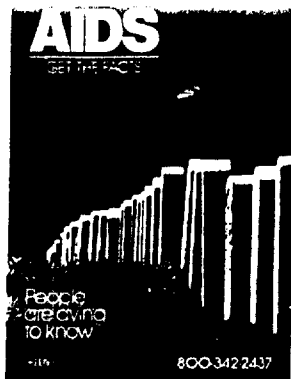
Enclosure

<input type="checkbox"/> AIDS	<input type="checkbox"/> Herpes
<input type="checkbox"/> Alcohol	<input type="checkbox"/> Mental Health
<input type="checkbox"/> Allergies	<input type="checkbox"/> Panic
<input type="checkbox"/> Alzheimers	<input type="checkbox"/> Poison Prevention
<input type="checkbox"/> Arthritis	<input type="checkbox"/> STDs
<input type="checkbox"/> Cholesterol	<input type="checkbox"/> Skin Cancer
<input type="checkbox"/> Colorectal Cancer	<input type="checkbox"/> Sleep Disorder
<input type="checkbox"/> Condom Week	<input type="checkbox"/> Stroke Prevention
<input type="checkbox"/> Depression	<input type="checkbox"/> Substance Abuse
<input type="checkbox"/> Diabetes	<input type="checkbox"/> Tobacco Dependence
<input type="checkbox"/> Fibromyalgia	<input type="checkbox"/> Women's Health

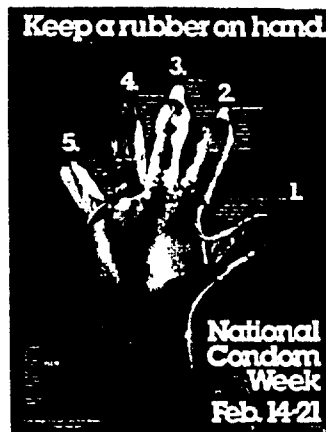
ColleaguePH



**T. D. & Family Planning Posters**



**THE CONDOM:**  
**Sensible, Safe**  
**and Sensual**



**ORDER FORM**

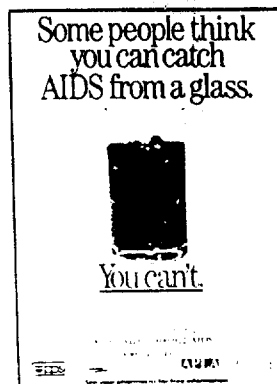
Please send me the following posters  
Check type and indicate quantity

- |                             |          |        |
|-----------------------------|----------|--------|
| _____FACTS ABOUT STD        |          |        |
| _____BLACK PREGNANT MAN     |          |        |
| _____CAUCASIAN PREGNANT MAN |          |        |
| _____LATINO PREGNANT MAN    |          |        |
| _____KEEP A RUBBER ON HAND  |          |        |
| _____WHAT CAN YOU GET       | 1 only   | \$5.00 |
| _____THE CONDOM             | 2-10     | \$4.75 |
| _____HERPES/THE CONDOM      | 11-50    | \$4.50 |
| _____CONDOM WHEEL           | 51 over  | \$4.25 |
| _____AIDS (get facts)       | 100 over | \$4.00 |
| _____AIDS (glass)           |          |        |

Enclosed please find my check  
for \$\_\_\_\_\_ for \_\_\_\_\_ posters.  
Make checks payable and mail to:

PPSI  
VD/Family Planning Program  
101 WEAS VALLEY BL

NAME \_\_\_\_\_  
ADDRESS \_\_\_\_\_ CITY \_\_\_\_\_




# PPSI PUBLIC HEALTH PROGRAMS

**Help us stop Arthritis before it stops you.**

SEE YOUR PHARMACIST FOR FREE INFORMATION

**The Arthritis Foundation**

**EMERGENCY AWARENESS MONTH—MAY**  
**Emergencies Don't Wait!**



SEE YOUR PHARMACIST FOR INFORMATION ON YOUR LOCAL EMERGENCY MEDICAL SERVICE

Kits and Materials Available

reach out for someone, not something


**DON'T MISUSE DRUGS**

SEE YOUR PHARMACIST OR PHYSICIAN ON CALL FOR MORE INFORMATION. DRUGS SAVING LIVES! 800-877-0640



Would you know it was you?

**The epileptic is so misunderstood**




**What you don't know about EPILEPSY can HURT!**

FOR INFORMATION AND FREE PHARMACEUTICAL OR YOUR PHARMACEUTICAL'S LOCAL EPILEPSY FACTS



Would you know it was you?

**Keep a rubber on hand.**



**National Condom Week**  
**Feb. 14/21**

**Children Act Fast... So Can Poisons**  
**PROTECT YOUR CHILDREN**  
says Jimmy Cridget



SEE YOUR PHARMACIST FOR FREE INFORMATION


NATIONAL POISON PREVENTION MONTH—FEBRUARY

Facts about

**STD**

STD can be prevented

**What can we get from using a condom?**



**Nothing... but pleasure and protection!**


SEE YOUR PHARMACIST FOR FREE INFORMATION ON LOCAL POISONING AND MEDICAL EMERGENCY PREVENTION. 800-877-0640

**INSIDE EVERY SMOKER IS AN EX-SMOKER.**



SEE YOUR PHARMACIST AND LEARN HOW TO QUIT SMOKING ON YOUR OWN. 800-877-0640

**THE CONDOM: Sensible, Safe and Sensual**




SEE YOUR PHARMACIST OR PHARMACEUTICAL FOR FREE INFORMATION ON LOCAL POISONING AND MEDICAL EMERGENCY PREVENTION. 800-877-0640

**2000 children will die this year from child abuse and neglect.**

**(CHILD ABUSE AND NEGLECT)**

SEE YOUR PHARMACIST FOR FREE INFORMATION ON LOCAL POISONING AND MEDICAL EMERGENCY PREVENTION. 800-877-0640

**A DISEASE YOU DON'T WANT TO THINK ABOUT IN A PLACE YOU DON'T WANT TO TALK ABOUT**



**COLORRECTAL CANCER**

SEE YOUR PHARMACIST FOR FREE INFORMATION ON LOCAL POISONING AND MEDICAL EMERGENCY PREVENTION. 800-877-0640

**NATIONAL DIABETES AWARENESS MONTH—NOVEMBER**

**You can live with DIABETES if you learn how!**

SEE YOUR PHARMACIST FOR FREE INFORMATION ON LOCAL POISONING AND MEDICAL EMERGENCY PREVENTION. 800-877-0640

**CHECK APPROPRIATE BOXES - FREE INFORMATION FOR PPSI MEMBERS.**

**CHECK APPROPRIATE BOXES - FREE KITS FOR PPSI MEMBERS.**

☐ Feb. 14-21  
☐ March  
☐ April  
☐ May  
☐ June  
☐ Sept.  
☐ Oct.  
☐ Nov.  
☐ Dec.

**in Members \$15./kit**

**SEND TO:**  
**PPSI**  
101 LUCAS VALLEY RD.  
H 210  
SAN RAFAEL, CA 94903

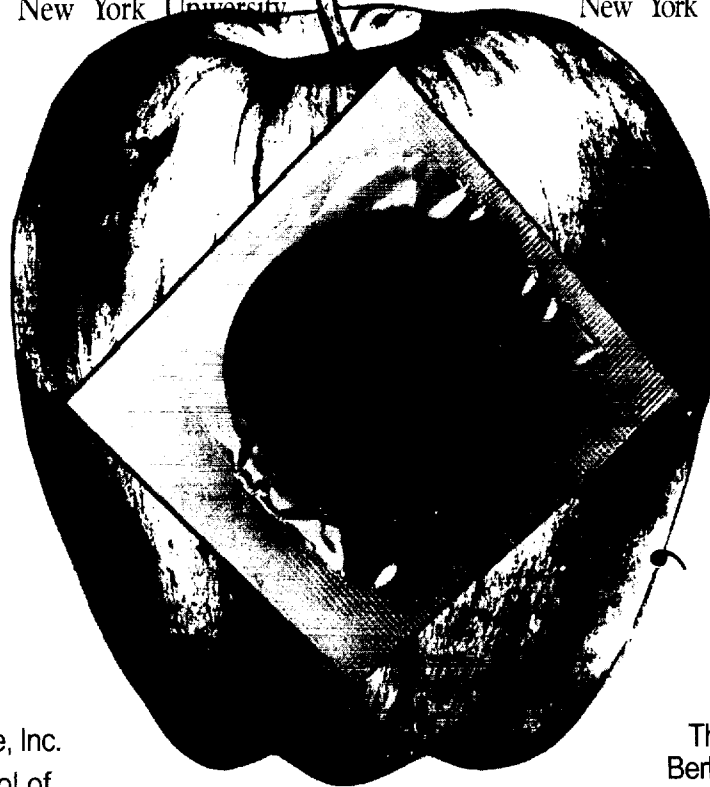
**National Condom Week**  
**Poison Prevention/Vision Care**  
**VD/Family Planning**  
**Arthritis/Emergency Awareness**  
**Child Abuse/Cancer in the Sun**  
**Cholesterol**  
**Drug Abuse/Pediculosis**  
**Diabetes/Epilepsy/Smoke-Out Day**  
**Colorectal Cancer**

3rd ANNUAL

Preliminary Program

# National Symposium on Overcoming Barriers to Condom Use

June 16-22, 1999  
New York University New York



Pharmacists Planning Service, Inc.  
Columbia University School of  
Public Health

The Condom Resource Center  
Advocates for Youth

Hunter College Center on AIDS,  
Drugs and Community Health

The Alan Guttmacher Institute

The National Coalition of STD  
Directors

## SPONSORED BY:

New York University School of  
Education, Department of  
Health Studies

Planned Parenthood, New York

Public Health Association of  
New York

University of California at Los  
Angeles, School of Public Health

The University of California at  
Berkeley, School of Public Health

American Social Health  
Association

Population Services  
International

The Institute for Healthcare  
Advancement

Planned Parenthood Federation  
of America



# Focusing on these Key Issues & New Developments

## Speakers Advisory Committee

The following list includes individuals who are assisting with the selection of speakers at the conference.

(\* Presented at Past Conferences)

Malcolm Potts, MD, PhD, Professor, UC Berkeley School of Public Health

Sally Guttmacher, PhD, Director, Masters of Public Health Programs, NYU

Allan Rosenfield, MD, Dean, Columbia University School of Public Health

Katherine Stone, MD, Division of STD, CDC

Paul J. Feldbaum, PhD, Family Health International

Katherine Forrest, MD, Past Medical Director, Planned Parenthood, Santa Clara, CA

Frederick S. Mayer, RPh, MPH, President, PPSI

Phil Harvey, President, DKT International

Adam Glickman, Co-Founder, Condomania

Daniel Bao, Executive Director, The Condom Resource Center

Nick Frenkelberg, PhD, Director, Hunter College Center on AIDS, Drugs and Community Health

Suzi Landolphi, Safer Sex Educator, Hot Sexy and Safer  
Kent Klindera, MPH, Advocates For Youth

- Trends in attitudes and usage— U.S. and international
- Advertising, media, and social marketing
- New technologies—urethane, elastomer, female condom, chemical barriers
- Technical update
- Budget cuts, managed care, and other political and financial changes affecting use
- Special populations — men, women, gay/lesbian/bi-sexual, youth, communities of color, immigrants and refugees
- Condoms, ethics, and the safer sex message
- Innovative programs

## Conference Objectives

- Share information on condom efficacy and technical developments
- Examine institutional, social, and individual factors which affect condom use
- Disseminate information on successful domestic and international programs for condom education, promotion and availability
- Recognize technologies to improve condoms
- Identify areas for research and action
- Provide a multidisciplinary forum for addressing condom-related issues, and increase public awareness of condom use

## Who Should Attend:

Community and public agencies involved in STD/HIV services and family planning, health educators, researchers, peer educators, condom companies, physicians, nurses and other clinical providers, pharmacists, health officials, agencies involved in condom marketing, and anyone interested in safer sex products.

## E-mail to:

Condoms for your public health, safe sex, and condom-related products!

A limited amount of tables available to exhibit to conference participants. Exhibitors receive full access to conference sessions, breakfast, snacks and beverages.  
For-Profit Companies \$500  
Non-Profit Organizations \$300

## Program Abstract Book

E-mail (condom@hol.com) a description of your condom-related program or research. Your description will be included in a booklet distributed to all conference participants. Please include: the name of the program, the time period it has operated, principal project staff, the target audience, key objectives and program elements, and any measures of effectiveness to date. Your abstract must fit into a 10 x 10 inch box using a 10 point font, larger, for readability.

## Program Poster Contest

You are invited to create a poster presentation (i.e. word, graph, and picture description in a 6 ft. x 4 ft. space) of your local condom-related program.

There will be prizes awarded for the programs judged most innovative and effective.

The purpose of the poster sessions is to share information in a visual manner about programs and research from around the country, and to provide recognition for outstanding programs. Your poster should vividly communicate key elements of your program, including the target audience, the process or methods by which the program or materials were developed, and the results and limitations of the implemented program.

All poster session applicants must E-mail a one page summary of their poster, postmarked no later than April 19, 1999.

To present a poster, you must register for the conference, be present to put up and take down your poster on the day it is presented, and submit a program description for the abstract book (see "program abstract book" information).

PPSI

101 Lucas Valley Road  
Suite 210-E  
San Rafael, CA 94903

Please Post



pharmacists planning service, inc.

101 Lucas Valley Road, Suite 210 • San Rafael, California 94903  
Tel: (415) 479-8628 • Fax: (415) 479-8608 • e-mail: [ppsi@aol.com](mailto:ppsi@aol.com)

April 20, 1999

Dear Conference Participant:

Thank you for registering for *the 3<sup>rd</sup> Annual National Symposium on Overcoming Barriers to Condom Use*.

This is confirmation for receipt of your registration and an update on the conference. The conference will be held at the *Loeb Student Center* on the Campus of New York University. New York University is located near Broadway and East 4<sup>th</sup> Street, in Manhattan, not far from Washington Square Park.

For a great place to stay, about ten minutes from the conference site, we recommend the headquarters hotel of the conference, *The Marriott World Trade Center* (212 938-9100). Normally the rooms at the Marriott are \$290 per night, but if you mention you are with Pharmacists Planning Service's Condom Conference they will give you the discount rate of \$170 per night. We have a list of other hotels as well.

We are looking forward to seeing you at the conference. We anticipate a large number of researchers, professors, clinicians, public health workers, manufacturers and students to attend the conference. We appreciate your joining this eclectic group of people with a common mission of preventing STDs, including HIV and unplanned pregnancy.

Enclosed please find a conference brochure to pass on to a colleague who might want to attend.

Thank you again for your interest and participation. If you have any questions, contact us by email at [PPSI@aol.com](mailto:PPSI@aol.com). See you in New York in June!

Sincerely,

David Silberman, MPH  
Conference Coordinator